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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 08/716,169 | 12/17/1996 | STEPHEN M. ANDERTON | 961125 | 5487 |

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| EXAMINER | |
|---|---|
| NOLAN, PATRICK J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1644 | |

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 08/716,169 | ANDERTON ET AL. | |
| | Examiner | Art Unit | |
| | Patrick J. Nolan | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *24-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 24-32 are pending.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The rejection of claims 24-31 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,268,170 has been removed in light of Applicant's arguments filed 9-22-05.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 24-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,268,170.

The '170 patent teaches administration of the entire MT hsp65 protein to treat autoimmune diseases. The '170 patent teaches administering peptides between 4-70 amino acids

in length starting at amino acid residue 171 and upto amino acid residue 240. The first 5 amino acids GVITV are identical between MT hsp65 and human hsp65, so administering a peptide comprising this sequence would anticipate the claimed invention, in addition the patent teaches using homologues of said peptides. Lastly, the peptides or polypeptides are to be administered orally.

The prior art teachings differ from the claimed invention by the specific length recitation of 7-30 amino acids.

However, it would have been prima facie obvious to one of skill ordinary skill in the art practicing the invention disclosed in the '170 patent to have been motivated to make multiple peptides of differing lengths, within the disclosed teaching of 4-70 amino acids and arrive at a single species within the genus of 7-30 amino acids, wherein said peptide encompassed amino acid residues 171-175 of the prior art disclosed MT hsp65 protein, since the entire length of the prior art protein fragment was only 70 amino acids and the disclosure specifically directed one of skill in the art to generate peptides of multiple lengths, deriving said peptides from the prior art disclosed 70 amino acid peptide,

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 24-25, 29-32 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments 9-22-05 have been fully considered but are not found persuasive.

Applicant argues the recitation of two species and the fact that additional species can be recognized or developed provides no reason for skepticism that the claimed invention is not adequately described. Further, Applicant argues the claims do not extend to any microbial

peptide from bacteria, only those that have a mammalian stress counterpart. Applicant also argues that the specification gives a fair description of many stress proteins which is in line with the breadth of the claims

The written description requirement is not based upon what those of skill in the art could readily develop using the claimed invention. It is based upon the actual written description of species in relation to the scope of the claims. Since Applicant has only two species described that meet the recitation of a microbial stress homologue that has a mammalian counterpart in concert with the limitations of the claims and the breadth reads upon many additional potential proteins derived from bacteria, protozoans eukaryotic parasites that have yet to even be isolated, the breadth of the claims is not in concert with written description of the claimed invention.

7. Claims 24-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nasal or oral administration of hsp65 peptides to treat Th1 mediated diseases, does not reasonably provide enablement for any other route of administration of peptides derived from any other microbial peptides to treat any inflammatory condition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant arguments filed 9-22-05 have been fully considered but are not found persuasive.

Applicant argues the specification amply explains administering a specific peptide to treat inflammatory disease and that a single lack of success as taught by the art is often overcome by routine adaptation of adjuvants and etc. and is not general evidence for lack of enablement. Lastly Applicant argues the Examiner has not brought forth any basis for any skepticism that the disclosed and claimed invention is either overbroad or does not work as asserted.

However, Applicant admits on the record the peptides work by causing the T cell population in the mucosa to generate IL-10, a known suppressor of Th1 mediated inflammatory disorders. Applicant uses the reference supplied by the Examiner for support of her contention. However, Wendling clearly teaches that parenteral administration did not suppress disease. In addition, Janeway et al., teaches that not all inflammatory diseases are T cell mediated. Since the mode of action of administering a hsp65 protein causes IL-10 production and subsequent down

regulation of T cell mediated events, one of skill in the art would not expect the hsp65 administration to be useful in inflammatory condition that are not T cell mediated. In addition it is noted that Attorney arguments as to what one of skill in the art can or cannot due cannot replace evidence where evidence is required. See MPEP 2145. Lastly, the use of the Wendling et al., reference is closest to the claimed invention. The working examples in the specification pre treat animals with the peptides before induction of arthritis, this is not equivalent to the customary treatment method in patients. Wendling treated subjects after induction, and determine peptide route administration was important in efficacy of the treatment. So, a single reference if it is the closest art to the actual claimed invention should be given more weight scientifically than pretreated experimental conditions as disclosed in the current application.

8. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
April 3, 2006